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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,182	07/11/2001	Albert C. Lardo	56245	1162

49383 7590 04/29/2009

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EXAMINER	
SHAY, DAVID M	
ART UNIT	PAPER NUMBER
3769	
MAIL DATE	DELIVERY MODE
04/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/904,182	LARDO ET AL.	
	Examiner	Art Unit	
	david shay	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 22, 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-83 and 86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-83 and 86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

It is argued by applicants that the provisional application "Notes" that "the present invention was documented in laboratory notebooks of the present inventors from March-June 2000". While there is a mention of laboratory notebooks of the inventors during this time period, it is insufficient to antedate the Pless reference for several reasons. Firstly, the reference in the provisional application is in reference to the "claimed invention" as filed therein. The claims filed with the provisional application relating to the invention currently claimed in the instant application merely recite the preamble of the instant claims. Thus this statement was not made with respect to the currently claimed invention. Secondly, even assuming, arguendo that the claims could be said to encompass the same subject matter, a simple statement in a disclosure is not the same as an affidavit sworn by the inventors and does not carry the same weight. Thirdly, the statement in the provisional application solely referred to the conception of the invention, while the affidavits in the prosecution history of the Pless patent are far more detailed than the one sentence reference in the provisional. Thirdly, the claims of the Pless patent, particularly claims 3 and 6 thereof, essentially claim the subject matter claimed in the instant application. Thus the Pless patent, with its attendant presumption of validity, cannot be overcome by swearing behind it. Thus applicant's arguments are not convincing.

Claims 61-63 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in combination with Diederich et al. Pless teaches ablating the os of the pulmonary vein using photodynamic therapy as set forth above. Diederich et al teach employing a balloon to direct various types of energy, including light to a specific area in the os of a pulmonary vein to produce a lesion that will form a conduction block and infusing contrast agent. It would have

been obvious to the artisan of ordinary skill to employ the phototherapeutic treatment of Pless in the method of Diederich et al, since Diederich et al teach that many methods may be used to produce the lesion, or to employ the guidance and imaging techniques of Diederich et al, in the method of Pless, since this is a known method for positively engaging the os of the pulmonary vein for ablation, as shown by Diederich et al and to administer the photosensitizer via perfusing the coronary arteries, or by intravenous injection, since these are not critical; do not require site specific administration of the photosensitizer; and provide no unexpected result, thus producing a method such as claimed.

Claims 64-67, 69-78, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in combination with Diederich et al as applied to claims 61-63 and 84 above, and further in combination with Leone. Leone teaches, a porous balloon constructed from a semi-permiable membrane which is inflated with and thereby delivers a photosensitizer to the tissue with which it is in contact, the balloon also houses an optical fiber which emits light to activate the photosensitizer. It would have been obvious to the artisan of ordinary skill to employ the phototherapeutic treatment balloon of Leone in the combined method of Pless and Diederich et al, since this would apply the photodynamic sensitizer directly to the tissue of interest, or to employ the pulmonary vein ablation technique of the combined method of Pless and Diederich et al in the method of Leone, since this would prevent arrhythmia, as taught by both Pless and Diederich et al, thus producing a method such as claimed.

Claims 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in combination with Diederich et al as applied to claims 61-63 and 84 above, and further in combination with Swanson. Swanson teaches, in addition to transmitting the energy, which can be laser light through a balloon, a guidance technique, which can include MRI; the energy application, which can include transmission of the tissue destroying energy through intervening media in contact with the tissue, to which the energy is essentially transparent; the application to atrial fibrillation; and incorporates by reference U.S. Patent No. 5,636,634, which discloses the infusion of saline or an anticoagulant. It would have been obvious to the artisan of ordinary skill to employ the phototherapeutic treatment of the combined method of Pless and Diederich et al in the method of Swanson, since this causes less trauma to the tissue, or to employ the guidance technique of Swanson, which can include MRI; the energy application, which can include transmission of the tissue destroying energy through intervening media in contact with the tissue, to which the energy is essentially transparent; and the application to atrial fibrillation in the method of Pless combined with Diederich et al, since this would assure that the application of energy was done in the proper place, and also be determinative of the proper endpoint for the procedure, thus producing a method such as claimed.

Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in combination with Diederich et al, as applied to claims 61-63 and 84 above, and further in combination with Rice et al. Rice et al teach that phthalocyanines are appropriate photosensitizers. It would have been obvious to the artisan of ordinary skill to employ

phthalocyanines as the photosensitizers, since these are effective as photosensitizers and Pless teaches no particular photosensitizer, thus producing a method such as claimed.

Applicant's arguments filed January 22, 2009 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769